

§ 862.1

862.2150 Continuous flow sequential multiple chemistry analyzer for clinical use.
862.2160 Discrete photometric chemistry analyzer for clinical use.
862.2170 Micro chemistry analyzer for clinical use.
862.2230 Chromatographic separation material for clinical use.
862.2250 Gas liquid chromatography system for clinical use.
862.2260 High pressure liquid chromatography system for clinical use.
862.2270 Thin-layer chromatography system for clinical use.
862.2300 Colorimeter, photometer, or spectrophotometer for clinical use.
862.2310 Clinical sample concentrator.
862.2320 Beta or gamma counter for clinical use.
862.2400 Densitometer/scanner (integrating, reflectance, TLC, or radiochromatogram) for clinical use.
862.2485 Electrophoresis apparatus for clinical use.
862.2500 Enzyme analyzer for clinical use.
862.2540 Flame emission photometer for clinical use.
862.2560 Fluorometer for clinical use.
862.2570 Instrumentation for clinical multiplex test systems.
862.2680 Microtitrator for clinical use.
862.2700 Nephelometer for clinical use.
862.2720 Plasma oncometer for clinical use.
862.2730 Osmometer for clinical use.
862.2750 Pipetting and diluting system for clinical use.
862.2800 Refractometer for clinical use.
862.2850 Atomic absorption spectrophotometer for clinical use.
862.2860 Mass spectrometer for clinical use.
862.2900 Automated urinalysis system.
862.2920 Plasma viscometer for clinical use.

Subpart D—Clinical Toxicology Test Systems

862.3030 Acetaminophen test system.
862.3035 Amikacin test system.
862.3040 Alcohol test system.
862.3050 Breath-alcohol test system.
862.3080 Breath nitric oxide test system.
862.3100 Amphetamine test system.
862.3110 Antimony test system.
862.3120 Arsenic test system.
862.3150 Barbiturate test system.
862.3170 Benzodiazepine test system.
862.3200 Clinical toxicology calibrator.
862.3220 Carbon monoxide test system.
862.3240 Cholinesterase test system.
862.3250 Cocaine and cocaine metabolite test system.
862.3270 Codeine test system.
862.3280 Clinical toxicology control material.
862.3300 Digitoxin test system.
862.3320 Digoxin test system.
862.3350 Diphenylhydantoin test system.

21 CFR Ch. I (4–1–12 Edition)

862.3360 Drug metabolizing enzyme genotyping system.
862.3380 Ethosuximide test system.
862.3450 Gentamicin test system.
862.3520 Kanamycin test system.
862.3550 Lead test system.
862.3555 Lidocaine test system.
862.3560 Lithium test system.
862.3580 Lysergic acid diethylamide (LSD) test system.
862.3600 Mercury test system.
862.3610 Methamphetamine test system.
862.3620 Methadone test system.
862.3630 Methaqualone test system.
862.3640 Morphine test system.
862.3645 Neuroleptic drugs radioreceptor assay test system.
862.3650 Opiate test system.
862.3660 Phenobarbital test system.
862.3670 Phenothiazine test system.
862.3680 Primidone test system.
862.3700 Propoxyphene test system.
862.3750 Quinine test system.
862.3830 Salicylate test system.
862.3840 Sirolimus test system.
862.3850 Sulfonamide test system.
862.3870 Cannabinoid test system.
862.3880 Theophylline test system.
862.3900 Tobramycin test system.
862.3910 Tricyclic antidepressant drugs test system.
862.3950 Vancomycin test system.

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

SOURCE: 52 FR 16122, May 1, 1987, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 862 appear at 73 FR 35341, June 23, 2008.

Subpart A—General Provisions

§ 862.1 Scope.

(a) This part sets forth the classification of clinical chemistry and clinical toxicology devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a pre-market notification submission for a device under part 807 cannot show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required in § 807.87.

(c) References in this part to regulatory sections of the Code of Federal

Regulations are to chapter I of title 21 unless otherwise noted.

(d) Guidance documents referenced in this part are available on the Internet at <http://www.fda.gov/cdrh/guidance.html>.

[52 FR 16122, May 1, 1987, as amended at 67 FR 58329, Sept. 16, 2002]

§ 862.2 Regulation of calibrators.

Many devices classified in this part are intended to be used with a calibrator. A calibrator has a reference value assigned to it which serves as the basis by which test results of patients are derived or calculated. The calibrator for a device may be (a) manufactured and distributed separately from the device with which it is intended to be used, (b) manufactured and distributed as one of several device components, such as in a kit of reagents, or (c) built-in as an integral part of the device. Because of the central role that a calibrator plays in the measurement process and the critical effect calibrators have on accuracy of test results, elsewhere in this part, all three of these types of calibrators (§§ 862.1150 and 862.3200 of this part) are classified into class II, notwithstanding the classification of the device with which it is intended to be used. Thus, a device and its calibrator may have different classifications, even if the calibrator is built into the device.

§ 862.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has

an approval under section 515 of the act FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraph (b) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28, 1976, including a device formerly marketed that has been substantially altered, is classified by statute (section 513(f) of the act) into class III without any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device before the device is commercially distributed unless it is reclassified. If FDA knows that a device being commercially distributed may be a "new" device as defined in this section because of any new intended use or other reasons, FDA may codify the statutory classification of the device into class III for such new use. Accordingly, the regulation for such a class III device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

§ 862.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

The exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is only to the extent